RULES
OF
THE TENNESSEE DEPARTMENT OF HEALTH
BOARD FOR LICENSING HEALTH CARE FACILITIES

CHAPTER 1200-8-29
STANDARDS FOR HOME CARE ORGANIZATIONS
PROVIDING HOME MEDICAL EQUIPMENT

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1200-8-29-.01 DEFINITIONS.

(1) Administrator. A person who:

(a) Is a licensed physician with at least one (1) year of supervisory or administrative experience in home health care, hospice care or related health programs; or

(b) Is a registered nurse with at least one (1) year of supervisory or administrative experience in home health care, hospice care or related health programs; or

(c) Has training and experience in health service administration and at least one (1) year of supervisory or administrative experience in home health care, hospice care or related health programs.

(2) Advance Directive. A written statement such as a living will, a durable power of attorney for health care or a do not resuscitate order relating to the provision of health care when the individual is incapacitated.

(3) Agency. A Home Care Organization providing home medical equipment.

(4) Board. The Tennessee Board for Licensing Health Care Facilities.

(5) Cardiopulmonary Resuscitation (CPR). The administering of any means or device to support cardiopulmonary functions in a patient, whether by mechanical devices, chest compressions, mouth-to-mouth resuscitation, cardiac massage, tracheal intubation, manual or mechanical ventilations or respirations, defibrillation, the administration of drugs and/or chemical agents intended to restore cardiac and/or respiratory functions in a patient where cardiac or respiratory arrest has occurred or is believed to be imminent.

(6) Clinical Note. A written and dated notation containing a patient assessment, responses to medications, treatments, services, any changes in condition and signed by a health team member who made contact with the patient.

(7) Commissioner. The Commissioner of the Tennessee Department of Health or his or her authorized representative.

(8) Competent. For the purpose of this chapter only, a patient who has decision-making capacity.

(9) Corrective Action Plan/Report. A report filed with the department by the facility after reporting an unusual event. The report must consist of the following:

(a) the action(s) implemented to prevent the reoccurrence of the unusual event,

(b) the time frames for the action(s) to be implemented,

(c) the person(s) designated to implement and monitor the action(s), and

(d) the strategies for the measurements of effectiveness to be established.

(10) Decision-making capacity. Decision-making capacity is shown by the fact that the person is able to understand the proposed procedure, its risks and benefits, and the available alternative procedures.

(11) Department. The Tennessee Department of Health.

(12) Do Not Resuscitate (DNR) Order. An order entered by the patient's treating physician in the patient's medical record which states that in the event the patient suffers cardiac or respiratory arrest, cardiopulmonary resuscitation should not be attempted. The order may contain limiting language to allow only certain types of cardiopulmonary resuscitation to the exclusion of other types of cardiopulmonary resuscitation.

(13) Hazardous Waste. Materials whose handling, use, storage and disposal are governed by local, state or federal regulations.

(14) Health care decision. A decision made by an individual or the individual’s health care decision-maker, regarding the individual’s health care including but not limited to:

(a) the selection and discharge of health-care providers and institutions;

(b) approval or disapproval of diagnostic tests, surgical procedures, programs of administration of medication, and orders not to resuscitate;

(c) directions to provide, withhold or withdraw artificial nutrition and hydration and all other forms of health care; and

(d) transfer to other health care facilities.

(15) Health Care Decision-maker. In the case of an incompetent patient, or a patient who lacks decision-making capacity, the patient’s health care decision-maker is one of the following: the patient’s health care agent as specified in an advance directive, the patient’s court-appointed legal guardian or conservator with health care decision-making authority, or the patient’s surrogate as determined pursuant to Rule 1200-8-29-.13 or T.C.A. §33-3-220.

(16) Home Care Organization. As defined by T.C.A. § 68-11-201, a "home care organization" provides home health services, home medical equipment services or hospice services to patients on an outpatient basis in either their regular or temporary place of residence.

(17) Home Medical Equipment.

(a) Medical equipment intended for use by the consumer including, but not limited to the following:

(Rule 1200-8-29-.01, continued)

1. A device, instrument, apparatus, machine, or other similar article whose label bears the statement: "Caution: Federal law requires dispensing by or on the order of a physician.";
2. Ambulating assistance equipment;
3. Mobility equipment;
4. Rehabilitation seating;
5. Oxygen care equipment and oxygen delivery systems;
6. Respiratory care equipment and respiratory disease management devices.
7. Rehabilitation environmental control equipment;
8. Ventilators;
9. Apnea monitors;
10. Diagnostic equipment;
11. Feeding pumps;
12. A bed prescribed by a physician to treat or alleviate a medical condition;
13. Transcutaneous electrical nerve stimulator;
14. Sequential compression devices; and
15. Neonatal home phototherapy devices.

(b) Home medical equipment does not include:

1. Medical equipment used or dispensed in the normal course of treating patients by hospitals and nursing facilities as defied in this part, other than medical equipment delivered or dispensed by a separate unit or subsidiary corporation of a hospital or nursing facility or agency that is in the business of delivering home medical equipment to an individual's residence;
2. Upper and lower extremity prosthetics and related orthotics;
3. Canes, crutches, walkers, and bathtub grab bars;
4. Medical equipment provided through a physician's office incident to a physician's service;
5. Equipment provided by a pharmacist which is used to administer drugs or medicine that can be dispensed only by a pharmacist; or
6. Enteral and parenteral equipment provided by a pharmacist.

(18) Home medical equipment provider. Any person who provides home medical equipment services.

(Rule 1200-8-29-.01, continued)

(19) Home medical equipment services. A service provided by any person who sells or rents home medical equipment for delivery to the consumer' place of residence in this state, regardless of the location of the home medical equipment provider.

(20) Incompetent. A patient who has been adjudicated incompetent by a court of competent jurisdiction and has not been restored to legal capacity.

(21) Infectious Waste. Solid or liquid wastes which contain pathogens with sufficient virulence and quantity such that exposure to the waste by a susceptible host could result in an infectious disease.

(22) Lacks Decision-Making Capacity. Lacks Decision-Making Capacity means the factual demonstration by the attending physician and the medical director, or the attending physician and another physician that an individual is unable to understand:

(a) A proposed health care procedure(s), treatment(s), intervention(s), or interaction(s);

(b) The risks and benefits of such procedure(s), treatment(s), intervention(s) or interaction(s); and

(c) The risks and benefits of any available alternative(s) to the proposed procedure(s), treatment(s), intervention(s) or interaction(s).

(23) Legal Conservator. Any person authorized to act for the patient pursuant to any provision of T.C.A. Title 34, Chapters 5 and 11 through 13.

(24) Legal Guardian. Any person authorized to act for the resident pursuant to any provision of T.C.A. §§34-5-102(4) or 34-11-101, or any successor statute thereto.

(25) Licensee. The person or entity to whom the license is issued. The licensee is held responsible for compliance with all rules and regulations.

(26) Licensed Practical Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(27) Life Threatening Or Serious Injury. Injury requiring the patient to undergo significant additional diagnostic or treatment measures.

(28) Medical Record. Medical histories, records, reports, clinical notes, summaries, diagnoses, prognoses, records of treatment and medication ordered and given, entries and other written electronic or graphic data prepared, kept, made or maintained in an agency that pertains to confinement or services rendered to patients.

(29) Medical Futile Treatment. Resuscitation efforts that cannot be expected either to restore cardiac or respiratory function to the patient or to achieve the expressed goals of the informed patient. In the case of the incompetent patient, the surrogate expresses the goals of the patient.

(30) Patient. Includes but is not limited to any person who is suffering from an acute or chronic illness or injury or who is crippled, convalescent or infirm, or who is in need of obstetrical, surgical, medical, nursing or supervisory care.

(31) Patient Abuse. Patient neglect, intentional infliction of pain, injury, or mental anguish. Patient abuse includes the deprivation of services by a caretaker which are necessary to maintain the health and welfare of a patient or resident; however, the withholding of authorization for or provision of medical care to any terminally ill person who has executed an irrevocable living will in accordance with the Tennessee Right to Natural Death Law, or other applicable state law, if the provision of such medical

care would conflict with the terms of such living will shall not be deemed "patient abuse" for purposes of these rules.

(32) Physician. A person currently licensed as such by the Tennessee Board of Medical Examiners or currently licensed by the Tennessee Board of Osteopathic Examination. For the purpose of this chapter only, a physician who is licensed to practice medicine or osteopathy in a state contiguous to Tennessee, who have previously provided treatment to the patient and has an ongoing physician-patient relationship with the patient for whom a referral is to be made, may refer a patient residing in this state to a home care organization providing hospice services duly licensed under this chapter. This shall not be construed as authorizing an unlicensed physician to practice medicine in violation of T.C.A. §§ 63-6-201 or 63-9-104.

(33) Registered Nurse. A person currently licensed as such by the Tennessee Board of Nursing.

(34) Shall or Must. Compliance is mandatory.

(35) Supervision. Authoritative procedural guidance by a qualified person for the accomplishment of a function or activity with initial direction and periodic inspection of the actual act of accomplishing the function or activity. Periodic supervision must be provided if the person is not a licensed or certified assistant, unless otherwise provided in accordance with these rules.

(36) Surrogate. The patient's conservator, or if none, a competent adult most likely to know the wishes of the patient with respect to the possible withholding of resuscitative services or withdrawal of resuscitative services.

(37) Unusual Event. The abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient that is not related to a natural course of the patient's illness or underlying condition.

(38) Unusual Event Report. A report form designated by the department to be used for reporting an unusual event.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-201, 68-11-202, 68-11-204, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed April 11, 2003; effective June 25, 2003. Amendment filed April 28, 2003; effective July 12, 2003.*

1200-8-29-.02 LICENSING PROCEDURES.

(1) No person, partnership, association, corporation or any state, county or local government unit, or any division, department, board or agency thereof, shall establish, conduct, operate or maintain in the State of Tennessee any Home Care Organization providing home medical equipment without having a license. A license shall be issued to the person or persons named and only for the premises listed in the application for licensure and for the geographic area specified by the certificate of need at the time of the original licensing. The name of the agency shall not be changed without first notifying the Department in writing. Licenses are not transferable or assignable and shall expire annually on June 30th. The license shall be conspicuously posted in the agency.

(2) In order to make application for a license:

(a) The applicant shall submit an application on a form prepared by the Department.

(b) Each applicant for a license shall pay an annual license fee of $400.00. The fee must be submitted with the application and is not refundable.

(c) The issuance of an application form is in no way a guarantee that the completed application will be accepted or that a license will be issued by the Department. Patients shall not be admitted to the agency until a license has been issued. Applicants shall not hold themselves out to the public as being an agency until the license has been issued. A license shall not be issued until the agency is in substantial compliance with these rules.

(d) The applicant must prove the ability to meet the financial needs of the agency.

(e) The applicant shall not use subterfuge or other evasive means to obtain a license, such as filing for a license through a second party when an individual has been denied a license or has had a license disciplined or has attempted to avoid an inspection and review process.

(3) A proposed change of ownership, including a change in a controlling interest, must be reported to the Department a minimum of thirty (30) days prior to the change. A new application and fee must be received by the Department before the license may be issued.

(a) For the purpose of licensing, the licensee of an agency has the ultimate responsibility for the operation of the agency, including the final authority to make or control operational decisions and legal responsibility for the business management. A change of ownership occurs whenever this ultimate legal authority for the responsibility of the agency's operation is transferred.

(b) A change of ownership occurs whenever there is a change in the legal structure by which the agency is owned and operated.

(c) Transactions constituting a change of ownership include, but are not limited to, the following:

1. Transfer of the agency's legal title;

2. Lease of the agency's operations;

3. Dissolution of any partnership that owns, or owns a controlling interest in, the agency;

4. One partnership is replaced by another through the removal, addition or substitution of a partner;

5. Removal of the general partner or general partners, if the agency is owned by a limited partnership;

6. Merger of an agency owner (a corporation) into another corporation where, after the merger, the owner's shares of capital stock are canceled;

7. The consolidation of a corporate agency owner with one or more corporations; or

8. Transfers between levels of government.

(d) Transactions which do not constitute a change of ownership include, but are not limited to, the following:

1. Changes in the membership of a corporate board of directors or board of trustees;

2. Two (2) or more corporations merge and the originally-licensed corporation survives;

3. Changes in the membership of a non-profit corporation;

(Rule 1200-8-29-.02, continued)

4. Transfers between departments of the same level of government; or

5. Corporate stock transfer or sales, even when a controlling interest.

(e) Management agreements are generally not changes of ownership if the owner continues to retain ultimate authority for the operation of the agency. However, if the ultimate authority is surrendered and transferred from the owner to a new manager, then a change of ownership has occurred.

(f) Sale/lease-back agreements shall not be treated as changes in ownership if the lease involves the agency's entire real and personal property and if the identity of the leasee, who shall continue the operation, retains the exact same legal form as the former owner.

(4) To be eligible for a license or renewal of a license, each agency shall be periodically inspected for compliance with these regulations. If deficiencies are identified, an acceptable plan of correction shall be established and submitted to the Department.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-216.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000.*

1200-8-29-.03 DISCIPLINARY PROCEDURES.

(1) The Board may suspend or revoke a license for:

(a) Violation of federal or state statutes;

(b) Violation of rules as set forth in this chapter;

(c) Permitting, aiding or abetting the commission of any illegal act by the agency;

(d) Conduct or practices found by the Board to be detrimental to the health, safety, or welfare of the patients of the agency; or

(e) Failure to renew the license.

(2) The Board may consider all factors which it deems relevant, including but not limited to the following, when determining sanctions:

(a) The degree of sanctions necessary to ensure immediate and continued compliance;

(b) The character and degree of impact of the violation on the health, safety and welfare of the patient in the agency.

(c) The conduct of the agency in taking all feasible steps or procedures necessary or appropriate to comply or correct the violation; and

(d) Any prior violations by the agency of statutes, rules or orders of the Board.

(3) When an agency is found by the Department to have committed a violation of this chapter, the Department will issue to the agency a statement of deficiencies. Within ten (10) days of receipt of the statement of deficiencies the agency must return a plan of correction indicating the following:

(a) How the deficiency will be corrected; and

(Rule 1200-8-29-.03, continued)

(b) The date upon which each deficiency will be corrected;

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, and 68-11-206 through 68-11-209.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000.*

1200-8-29-.04 ADMINISTRATION.

(1) Governing Body. The licensee shall assume full legal authority and responsibility for the operation of the agency. The governing body shall appoint a qualified manager, arrange for professional advice, adopt and periodically review written bylaws or an acceptable equivalent, and oversee the management and fiscal affairs of the agency. The name and address of each officer, director, and owner shall be disclosed. If the agency is a corporation, all ownership interests of five (5) percent or more (direct or indirect) shall also be disclosed.

(2) Manager. The manager shall organize and direct the agency's ongoing functions; maintain ongoing communication between and among the governing body, the professional personnel and the staff; employ qualified personnel, ensure adequate staff education and evaluation for all personnel involved in direct care of the patient; ensure the accuracy of public information materials and activities; and implement an effective accounting system. A person with sufficient experience and training shall be authorized in writing to assume temporary duty during the manager's short-term absence. Any change of managers shall be reported to the Department within fifteen (15) days.

(3) Organization Structure. The agency's structure is such that responsibility and accountability for the program are clearly defined. An organizational chart (A) shows the relationship of the manager to the governing body; (B) clearly identifies lines of supervision; and (C) accurately defines the chain of command for in-home personnel.

(4) Accreditation. Any home medical equipment provider accredited by the Joint Commission on Accreditation of the Health Care Organizations may submit documents evidencing current accreditation and shall be presumed to comply with the requirements of the Board. Licensing of a home medical equipment provider which has been accredited by the Joint Commission on Accreditation of Health Care Organizations shall become effective upon written notification from the Board's staff that the accreditation meets the standards set out in the rules and regulations promulgated pursuant to T.C.A. §§ 68-11-201, et seq.

(5) Personnel. Employees shall be qualified for the positions they hold and meet the education, training, and experience requirements defined by the agency.

(a) All employees shall receive and participate in an orientation program prior to assuming patient care responsibilities. The agency's written orientation plan shall outline topics to be covered; attendance requirements; method to verify topics discussed; a description of the orientation process; and the orientation plan shall include, but is not limited to:

1. Review of the individual's job description and duties to be performed;

2. Organizational chart;

3. Supervision;

4. Recordkeeping and reporting;

5. Confidentiality;

6. Patient's rights and responsibilities;

7. Pertinent personnel policies; and

8. Skills validation, as applicable.

(b) The agency shall maintain a personnel file for each employee which contains the following information:

1. A completed application;

2. References;

3. Work experience;

4. Educational preparation;

5. Job description which lists the minimum education, training, and experience requirement; job responsibilities; and title of immediate supervisor;

6. Annual performance appraisal or individual evaluations on specific job descriptions which include demonstrated current competency and proof that performance appraisal results were shared with employee;

7. Prior training;

8. Proof of orientation;

9. Evidence of current license, if applicable; and

10. Documentation of health screening, when mandated.

(i) Pre-employment and annual TB screening for job classifications subject to occupational exposure; and

(ii) Each employee with occupational exposure to the hepatitis B virus is offered the hepatitis B Vaccine (HBV) inoculation to protect against hepatitis B infection.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-1-222.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000.*

1200-8-29-.05 ADMISSIONS, DISCHARGE AND TRANSFERS.

(1) The agency only admits patients whose needs can be met by the services the agency provides.

(a) There shall be written policies and procedures and an organizational process that indicates employees with the necessary skill and training are assigned to assess the level and type of care/service required by patients referred to the agency, and to determine whether the patient is eligible for admission based on the agency's criteria and availability of services to meet the patient's needs. There shall also be a reasonable time frame in which the patient's eligibility for admission is assessed which takes into account the patient's service needs.

(b) There shall be a written policy that addresses the agency’s compliance with federal, state, and local anti-discrimination laws in the selection of patients.

(Rule 1200-8-29-.05, continued)

(2) Patients shall be transferred or referred to other organizations/agencies in the community when service needs are identified by staff or patients which cannot be met by the agency.

(3) When a patient is discharged, a summary of the significant findings and events of the patient's care, the patient's condition on discharge and the recommendation and arrangement for future care, if any, is required.

(4) The agency shall ensure that no person, on the grounds of race, color, national origin or handicap, will be excluded from participation in, be denied benefits of, or otherwise be subjected to discrimination in the provision of any care or service of the agency. The agency shall protect the civil rights of patients under the Civil Rights Act of 1964 and Section 504 of the Rehabilitation Act of 1973.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000.*

1200-8-29-.06 BASIC AGENCY FUNCTIONS.

(1) Patient Instruction. The agency shall have written guidelines relating to patient and/or caregiver training and education that includes at a minimum:

(a) Financial responsibilities;

(b) Equipment use and maintenance;

(c) Patient rights and responsibilities;

(d) Emergency/back-up systems and trouble shooting procedures, if applicable; and

(e) How to contact the agency during regular business hours and after hours, if applicable.

(2) Infection Control. The agency shall have written policies and procedures relating to infection control. Employees shall consistently follow infection control procedures in the provision of care to the agency's patients. The written policies and procedures at a minimum must address standards and education of staff about:

(a) Infection control measures;

(b) Handwashing;

(c) Use of universal precautions and personal protective equipment;

(d) Appropriate cleaning and disinfection of reusable equipment and supplies; and,

(e) Disposal of regulated waste.

(3) In-Home Safety. The agency shall educate staff, patients, and caregivers about basic home safety related to the use of equipment delivered to the home. There shall be a procedure for reporting and documenting all incidents. There shall be an incident report form and identification of the types of situations that should be reported and documented.

(4) Equipment Management.

(Rule 1200-8-29-.06, continued)

(a) Client-ready equipment shall be durable in nature, sanitized, and in proper working order. The agencyzation shall have clearly defined guidelines for the cleaning, storage, and transportation of client-ready equipment. These guidelines shall include, but are not limited to:

1. Separation of clean and unclean equipment;

2. Appropriate warehousing and tagging of equipment;

3. Use of appropriate cleaning agents, as directed by the manufacturer;

4. Routine maintenance of equipment; and

5. Separation of inoperative equipment.

(b) Agency employees shall be qualified to deliver, perform environmental assessments, set up, and demonstrate safe and proper use of all home medical equipment according to manufacturer's guidelines.

(c) Agency guidelines shall clearly define training, qualifications, and skills validation required by employees to perform routine maintenance and repairs of all home medical equipment. Routine maintenance, preventive maintenance, and repairs shall be performed according to manufacturer's guidelines. Agency employees shall only perform repair services within their respective areas of documented training and expertise. There shall be guidelines that define appropriate use of outside repair sources.

(d) The agency shall have written guidelines for accurate performance quality tracking of equipment in compliance with the FDA's Medical Device Tracking program and facilitate any recall notices sent by the manufacturer. These guidelines shall address the:

1. Immediate removal from equipment inventory;

2. Notification to the client; and

3. Exchange of equipment in the field.

(e) Disposition of recalled inventory shall be handled according to manufacturer's guidelines.

(f) Only durable medical equipment shall be returned to the company for processing. The agency shall have written policies and procedures for processing contaminated or soiled durable medical equipment and shall be in compliance with universal precautions. Guidelines shall specify the separation of dirty equipment from client ready equipment in the warehouse and delivery vehicles.

(5) Physical Location. Each parent and/or branch shall:

(a) Be located in Tennessee;

(b) Be staffed during normal business hours and have a working telephone;

(c) Be used for the dispensing, servicing, and storage of home medical equipment or related health care services;

(d) Meet all local zoning requirements; and

(Rule 1200-8-29-.06, continued)

(e) Have all required current licenses and/or permits conspicuously posted in the agency.

(6) Additional Compliance Requirements. The agency shall comply with all federal, state, and local laws and regulations.

(a) Written policies and procedures shall be established and implemented by the agency regarding compliance with all applicable federal, state, and local laws and regulations.

(b) The agency shall comply with the following supplier standards:

1. Fill orders from its own inventory or inventory of other companies with which it has contracts to fill such orders, or fabricates or fits items for sale from supplies it buys under a contract;

2. Oversee delivery of items that the supplier ordered for the patient. The supplier is also responsible to assure delivery of large items to the patient;

3. Honor all warranties, express or implied, under applicable state law;

4. Answer questions or complaints about an item or use of an item that is sold or rented to the patient. If the patient has questions, the supplier will refer the patient to the appropriate carrier;

5. Maintain and repair directly, or through a service contract with another company, items it rents to a patient;

6. Accept returns for substantial medical equipment;

7. Provide the following disclosure information to the department:

(i) The identity of each person having a five percent (5%) or more ownership or controlling interest in the agency.

(ii) The identity of subcontractors in which the agency has a five percent (5%) or more ownership interest;

(iii) At the time such information is disclosed or at any time during the three (3) year period preceding the date such information is supplied, managing employees of the agency, persons having five percent (5%) or more ownership or controlling interest, and subcontractors in which the agency has five percent (5%) or more ownership interest must disclose any other entity providing items or services that receives payment under title XVIII; and

(iv) Managing employees of the agency, persons having five percent (5%) or more ownership or controlling interest, and subcontractors in which the agency has five percent (5%) or more ownership interest must disclose any penalties, assessments, or exclusions assessed against such person under Section 1128, 1128A, or 1128B of the Social Security Act;

8. Maintain general and product liability insurance; and

9. Disclose consumer information to each patient. This consists of a copy of the supplies standards to which it must conform.

(Rule 1200-8-29-.06, continued)

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-209, and 68-11-304.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000.*

1200-8-29-.07 RESERVED.

1200-8-29-.08 RESERVED.

1200-8-29-.09 RESERVED.

1200-8-29-.10 INFECTIOUS AND HAZARDOUS WASTE.

(1) Each agency must develop, maintain and implement written policies and procedures for the definition and handling of its infectious and hazardous waste. These policies and procedures must comply with the standards of this rule and all other applicable state and federal regulations.

(2) The following waste shall be considered to be infectious waste:

(a) Waste human blood and blood products such as serum, plasma, and other blood components;

(b) All discarded sharps (including but not limited to, hypodermic needles, syringes, pasteur pipettes, broken glass, scalpel blades) used in patient care; and

(c) Other waste determined to be infectious by the agency in its written policy.

(3) Waste must be packaged in a manner that will protect waste handlers and the public from possible injury and disease that may result from exposure to the waste. Such packaging must provide for containment of the waste from the point of generation up to the point of proper treatment or disposal. Packaging must be selected and utilized for the type of waste the package will contain, how the waste will be treated and disposed, and how it will be handled and transported prior to treatment and disposal.

(a) Contaminated sharps must be directly placed in leakproof, rigid and puncture-resistant containers which must then be tightly sealed.

(b) Infectious and hazardous waste must be secured in fastened plastic bags before placement in a garbage can with other household waste.

(c) Reusable containers for infectious waste must be thoroughly sanitized each time they are emptied, unless the surfaces of the containers have been completely protected from contamination by disposable liners or other devices removed with the waste.

(4) After packaging, waste must be handled, transported and stored by methods ensuring containment and preserving the integrity of the packaging, including the use of secondary containment where necessary.

(5) Waste must be stored in a manner which preserves the integrity of the packaging, inhibits rapid microbial growth and putrefaction, and minimizes the potential of exposure or access by unknowing persons. Waste must be stored in a manner and location which affords protection from animals, precipitation, wind and direct sunlight, does not present a safety hazard, does not provide a breeding place or food source for insects or rodents, and does not create a nuisance.

(6) In the event of spills, ruptured packaging, or other incidents where there is a loss of containment of waste, the agency must ensure that proper actions are immediately taken to:

(a) Isolate the area;

(b) Repackage all spilled waste and contaminated debris in accordance with the requirements of this rule; and

(c) Sanitize all contaminated equipment and surfaces appropriately.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000.*

1200-8-29-.11 RECORDS AND REPORTS.

(1) A yearly statistical report, the "Joint Annual Report of Home Care Organizations," shall be submitted to the Department. The forms are mailed to each home care organization by the Department each year. The forms must be completed and returned to the Department as requested.

(2) Unusual events shall be reported by the facility to the Department of Health in a format designed by the Department within seven (7) business days of the date of the identification of the abuse of a patient or an unexpected occurrence or accident that results in death, life threatening or serious injury to a patient.

(a) The following represent circumstances that could result in an unusual event that is an unexpected occurrence or accident resulting in death, life threatening or serious injury to a patient, not related to a natural course of the patient's illness or underlying condition. The circumstances that could result in an unusual event include, but are not limited to:

1. medication errors;

2. aspiration in a non-intubated patient related to conscious/moderate sedation;

3. intravascular catheter related events including necrosis or infection requiring repair or intravascular catheter related pneumothorax;

4. volume overload leading to pulmonary edema;

5. blood transfusion reactions, use of wrong type of blood and/or delivery of blood to the wrong patient;

6. perioperative/periprocedural related complication(s) that occur within 48 hours of the operation or the procedure, including a procedure which results in any new central neurological deficit or any new peripheral neurological deficit with motor weakness;

7. burns of a second or third degree;

8. falls resulting in radiologically proven fractures, subdural or epidural hematoma, cerebral contusion, traumatic subarachnoid hemorrhage, and/or internal trauma, but does not include fractures resulting from pathological conditions;

9. procedure related incidents, regardless of setting and within thirty (30) days of the procedure and includes readmissions, which include:

(i) procedure related injury requiring repair or removal of an organ;

(ii) hemorrhage;

(Rule 1200-8-29-.11, continued)

(iii) displacement, migration or breakage of an implant, device, graft or drain;

(iv) post operative wound infection following clean or clean/contaminated case;

(v) any unexpected operation or reoperation related to the primary procedure;

(vi) hysterectomy in a pregnant woman;

(vii) ruptured uterus;

(viii) circumcision;

(ix) incorrect procedure or incorrect treatment that is invasive;

(x) wrong patient/wrong site surgical procedure;

(xi) unintentionally retained foreign body;

(xii) loss of limb or organ, or impairment of limb if the impairment is present at discharge or for at least two (2) weeks after occurrence;

(xiii) criminal acts;

(xiv) suicide or attempted suicide;

(xv) elopement from the facility;

(xvi) infant abduction, or infant discharged to the wrong family;

(xvii) adult abduction;

(xviii) rape;

(xix) patient altercation;

(xx) patient abuse, patient neglect, or misappropriation of resident/patient funds;

(xxi) restraint related incidents; or

(xxii) poisoning occurring within the facility.

(b) Specific incidents that might result in a disruption of the delivery of health care services at the facility shall also be reported to the department, on the unusual event form, within seven (7) days after the facility learns of the incident. These specific incidents include the following:

1. strike by the staff at the facility;

2. external disaster impacting the facility;

3. disruption of any service vital to the continued safe operation of the facility or to the health and safety of its patients and personnel; and

4. fires at the facility which disrupt the provision of patient care services or cause harm to patients or staff, or which are reported by the facility to any entity, including but not limited to a fire department, charged with preventing fires.

(c) For health services provided in a "home" setting, only those unusual events actually witnessed or known by the person delivering health care services are required to be reported.

(d) Within forty (40) days of the identification of the event, the facility shall file with the department a corrective action report for the unusual event reported to the department. The department's approval of a Corrective Action Report will take into consideration whether the facility utilized an analysis in identifying the most basic or causal factor(s) that underlie variation in performance leading to the unusual event by (a) determining the proximate cause of the unusual event, (b) analyzing the systems and processes involved in the unusual event, (c) identifying possible common causes, (d) identifying potential improvements, and (e) identifying measures of effectiveness. The corrective action report shall either: (1) explain why a corrective action report is not necessary; or (2) detail the actions taken to correct any error identified that contributed to the unusual event or incident, the date the corrections were implemented, how the facility will prevent the error from recurring in the future and who will monitor the implementation of the corrective action plan.

(e) The department shall approve in writing, the corrective action report if the department is satisfied that the corrective action plan appropriately addresses errors that contributed to the unusual event and takes the necessary steps to prevent the recurrence of the errors. If the department fails to approve the corrective action report, then the department shall provide the facility with a list of actions that the department believes are necessary to address the errors. The facility shall be offered an informal meeting with the Commissioner or the Commissioner's representative to attempt to resolve any disagreement over the corrective action report. If the department and the facility fail to agree on an appropriate corrective action plan, then the final determination on the adequacy of the corrective action report shall be made by the Board after a contested case hearing.

(f) The event report reviewed or obtained by the department shall be confidential and not subject to discovery, subpoena or legal compulsion for release to any person or entity, nor shall the report be admissible in any civil or administrative proceeding other than a disciplinary proceeding by the department or the appropriate regulatory board. The report is not discoverable or admissible in any civil or administrative action except that information in any such report may be transmitted to an appropriate regulatory agency having jurisdiction for disciplinary or license sanctions against the impacted facility. The department must reveal upon request its awareness that a specific event or incident has been reported.

(g) The department shall have access to facility records as allowed in Title 68, Chapter 11, Part 3. The department may copy any portion of a facility medical record relating to the reported event unless otherwise prohibited by rule or statute. This section does not change or affect the privilege and confidentiality provided by T.C.A. §63-6-219.

(h) The department, in developing the unusual event report form, shall establish an event occurrence code that categorizes events or specific incidents by the examples set forth above in (a) and (b). If an event or specific incident fails to come within these examples, it shall be classified as "other" with the facility explaining the facts related to the event or incident.

(i) This does not preclude the department from using information obtained under these rules in a disciplinary action commenced against a facility, or from taking a disciplinary action against a facility. Nor does this preclude the department from sharing such information with any appropriate governmental agency charged by federal or state law with regulatory oversight of

the facility. However, all such information must at all times be maintained as confidential and not available to the public. Failure to report an unusual event, submit a corrective action report, or comply with a plan of correction as required herein may be grounds for disciplinary action pursuant to T.C.A. §68-11-207.

(j) The affected patient and/or the patient's family, as may be appropriate, shall also be notified of the event or incident by the facility.

(k) During the second quarter of each year, the Department shall provide the Board an aggregate report summarizing by type the number of unusual events and incidents reported by facilities to the Department for the preceding calendar year.

(l) The Department shall work with representatives of facilities subject to these rules, and other interested parties, to develop recommendations to improve the collection and assimilation of specific aggregate health care data that, if known, would track health care trends over time and identify system-wide problems for broader quality improvement. The goal of such recommendations should be to better coordinate the collection of such data, to analyze the data, to identify potential problems and to work with facilities to develop best practices to remedy identified problems. The Department shall prepare and issue a report regarding such recommendations.

(3) Patient Records shall be maintained for each patient who receives in-home services. The patient record must contain detailed, accurate documentation that reflects all of the services or care provided, directly or by contract. The patient record shall contain at a minimum the following:

(a) Documentation of patient education and instruction;

(b) Physician orders as required;

(c) Documentation that patient has been fully informed of patient rights and responsibilities and at a minimum, the right to:

1. Be fully informed in advance about care and treatment to be provided by the agency;

2. Be fully informed in advance of any changes in the care or treatment to be provided by the agency when those changes may affect the patient's well-being;

3. Voice grievances without fear of discrimination or reprisal;

4. Confidentiality of personal information;

5. Have one's property treated with respect; and

6. Be fully informed of the agency's telephone number for information, questions, and/or complaints about services provided by the agency and a description of the process for investigating and resolving complaints. The agency shall investigate and resolve all patient complaints and document the results in a timely manner. The agency shall label all equipment with the name, address, and telephone number of the agency.

(4) Patient Confidentiality. The agency shall have written policies dealing with patient information. Patient records shall contain signed release of information statements/forms when the agency bills a third-party payor or shares information with others outside the agency. Patient confidentiality polices will address, at a minimum, the following:

(Rule 1200-8-29-.11, continued)

(a) A definition of confidential information;

(b) Persons/positions authorized to release confidential information;

(c) Conditions which warrant release of confidential information;

(d) Persons to whom confidential information may be released;

(e) Policies and procedures for obtaining signatures on, using, and filing release of information forms;

(f) Who has authority to review patient records; and

(g) A statement that training in confidentiality is mandatory for all employees, so that personnel are knowledgeable about and consistently follow confidentiality polices and procedures.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-207, 68-11-209, 68-11-210, 68-11-211, and 68-11-213.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed April 11, 2003; effective June 25, 2003.*

1200-8-29-.12 PATIENT RIGHTS.

(1) Each patient has at least the following rights:

(a) To privacy in treatment and personal care;

(b) To be free from mental and physical abuse. Should this right be violated, the agency must notify the Department within five (5) business days and the Tennessee Department of Human Services, Adult Protective Services immediately;

(c) To refuse treatment. The patient must be informed of the consequences of that decision, and the refusal and its reason must be reported to the treating physician and documented in the medical record;

(d) To refuse experimental treatment and drugs. The patient's written consent for participation in research must be obtained and retained in his or her medical record; and

(e) To have his or her records kept confidential and private. Written consent by the patient must be obtained prior to release of information except to persons authorized by law. If the patient is mentally incompetent, written consent is required from the patient's legal representative. The agency must have policies to govern access and duplication of the patient's record.

(2) Each patient has a right to self-determination, which encompasses the right to make choices regarding life-sustaining treatment, including resuscitative services. This right of self-determination may be effectuated by an advance directive.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000.*

1200-8-29-.13 POLICIES AND PROCEDURES FOR HEALTH CARE DECISION-MAKING FOR INCOMPETENT PATIENTS.

(1) Pursuant to this Rule, each home medical equipment agency shall maintain and establish policies and procedures governing the designation of a health care decision-maker for making health care decisions for a patient who is incompetent or who lacks decision-making capacity, including but not limited to allowing the withholding of CPR measures from individual patients. The policies and procedures for determining when resuscitative services may be withheld must respect the patient's rights of self-determination. The home medical equipment agency must inform the patient and/or the patient's health care decision-maker of these policies and procedures upon admission or at such time as may be appropriate.

(2) The home medical equipment agency should identify, after consultation with the family or responsible party, the name of the health care decision-maker for a patient who is incompetent or who lacks decision-making capacity, who will be responsible, along with the treating physician, for making health care decisions, including but not limited to deciding on the issuance of a DNR order.

(3) Health care decisions made by a health care decision-maker must be made in accord with the patient's individual health care instructions, if any, and other wishes to the extent known to the health care decision-maker. If the patient's specific wishes are not known, decisions are to be made in accord with the health care decision-maker's determination of the patient's desires or best interests in light of the personal values and beliefs of the patient to the extent they are known.

(4) In the case of a patient who lacks decision-making capacity and who has not appointed an individual to act on his or her behalf pursuant to an advance directive and who does not have a court-appointed guardian or conservator with health care decision-making authority, documentation in the medical record must identify the patient's surrogate to make health care decisions on the patient's behalf.

(a) The patient's surrogate shall be an adult who:

1. has exhibited special care and concern for the patient, who is familiar with the patient's personal values, and who is reasonably available; and

2. consideration shall if possible be given in order of descending preference for service as a surrogate to:

(i) the patient's spouse,

(ii) the patient's adult child,

(iii) the patient's parent,

(iv) the patient's adult sibling,

(v) any other adult relative of the patient, or

(vi) any other adult who satisfies the requirement under part 1 above.

(b) If none of the individuals eligible to act as a surrogate under subparagraph (a), is reasonably available, the patient's treating physician may make health care decisions for the patient after the treating physician either (i) consults with and obtains the recommendations of an institutional ethics committee, or (ii) consults with a second physician who (A) is not directly involved in the patient's health care; (B) either (i) does not serve in a capacity of decision-making or influence or responsibility over the treating physician, or (ii) for whom the treating physician does not exert decision-making, influence or responsibility; and (C) concurs with the treating physician's decision. For the purposes of this rule, "institutional ethics committee"

means a committee of a licensed health care institution which renders advice concerning ethical issues involving health care.

(5) All patients shall be presumed as having consented to CPR unless there is documentation in the medical record that the patient has specified that a DNR order be written. DNR orders may be written to exclude any portion of the CPR measures deemed to be unacceptable.

(6) In the case of an incompetent patient who has appointed an attorney in fact to act on his or her behalf pursuant to an advance directive or who has a court-appointed guardian or conservator with health care decision-making authority, documentation in the medical record must reflect that the attorney in fact, guardian or conservator has specified that a DNR order be written. In the case of a patient who lacks decision-making capacity and who has not appointed an individual to act on his or her behalf pursuant to an advance directive and who does not have a court-appointed guardian or conservator with health care decision-making authority, documentation in the medical record must identify the patient's surrogate to make health care decisions on the patient's behalf, and reflect that the patient's surrogate and the patient's treating physician have mutually specified that a DNR order be written.

(7) CPR may be withheld from the patient if in the judgment of the treating physician an attempt to resuscitate would be medically futile. Withholding and withdrawal of resuscitative services shall be regarded as identical for the purposes of these regulations.

(8) Procedures for periodic review of DNR orders must be established and maintained. The home medical equipment agency must have procedures for allowing revocation or amending DNR orders by the patient, the patient's health care decision-maker, or treating physician. Such change shall be documented in the medical record.

(9) Any treating physician who refuses to enter a DNR order in accordance with provisions set forth above, or to comply with a DNR order, shall promptly advise the patient or the patient's health care decision-maker of this decision. The treating physician shall then:

(a) Make a good faith attempt to transfer the patient to another physician who will honor the DNR order; and,

(b) Permit the patient to obtain another physician.

(10) Each home medical equipment agency shall establish, and set forth in writing, a mediation process to deal with any dispute regarding health care decisions, including DNR orders, or the determination of the health care decision-maker.

(11) This rule does not alter any requirements imposed by state or federal law, where applicable, including Title 33, the mental health and developmental disabilities law.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, 68-11-204, 68-11-206, 68-11-209, and 68-11-224.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000. Amendment filed April 28, 2003; effective July 12, 2003.*

1200-8-29-.14 DISASTER PREPAREDNESS.

(1) All agencies shall establish and maintain communications with the local office of the Tennessee Emergency Management Agency. This includes the provision of the information and procedures that are needed for the local comprehensive emergency plan. The agency shall cooperate, to the extent possible, in area disaster drills and local emergency situations.

(Rule 1200-8-29-.14, continued)

(2) All agencies shall establish and maintain a file of documents demonstrating communications and cooperation with the local agency.

(3) Emergency Preparedness Plan. All agencies shall establish procedures for emergency response to provide continued service, 24 hours a day, seven days a week, to the patient base on service interruption for apnea monitors, ventilators, suction pumps and oxygen. The agency shall have written policies and procedures for back-up systems for equipment or power failure for apnea monitors, ventilators, suction pumps and oxygen.

Authority: *T.C.A. §§4-5-202, 4-5-204, 68-11-202, and 68-11-209.* ***Administrative History:*** *Original rule filed August 24, 2000; effective November 7, 2000.*